REMARKS

Claims 1-3, 5-7, 12-14, 18, 19, 37, 39 and 44 have been amended. In compliance with 37 C.F.R. §121(c)(3), a clean version of the entire set of pending claims is being submitted, as is a marked-up version showing changes in the amended claims relative to the previous version of the claims.

New claims 47-49 are submitted for prosecution. Support for the subject matter of claims 47-49 may be found in claim 1 as filed.

Claims 1-23 and 37-49 remain in the application. Of these, claim 1, 19, 23, 37, 43 and 47-49 are independent apparatus claims.

Claims 19-22 are rejected under obviousness-type double patenting over claims 1-4 of copending Application Serial No. 09/231,320 (the '320 Application). Applicant notes that claims 1-4 of the '320 Application were canceled in the Response to Restriction Requirement mailed October 3, 2000. Therefore, Applicant respectfully requests that this rejection be withdrawn. Claims 19-22 are also rejected under obviousness-type double patenting over claims 1-4 of copending Application Serial No. 10/021,549 (the '549 Application). Applicant will submit a terminal disclaimer based on the '549 Application upon indication of allowable subject matter, but for the double patenting rejection.

Claim 23 is rejected under obviousness-type double patenting over claim 6 of copending Application Serial No. 09/231,320 (the '320 Application). Applicant notes that claim 6 of the '320 Application was canceled in the Response to Restriction Requirement mailed October 3, 2000. Therefore, Applicant respectfully requests that this rejection be withdrawn. Claim 23 is also rejected under obviousness-type double patenting over claim 6 of copending Application Serial No. 10/021,549 (the '549 Application). Applicant notes that claims 2-15 of the '549 Application were canceled in a Preliminary Amendment mailed December 12, 2001. Therefore, Applicant respectfully requests that this rejection be withdrawn.

Claim 37 is rejected under obviousness-type double patenting over claim 2 of U.S. Patent No. 6,395,026 (the '026 Patent) and claim 15 of copending Application Serial No. 10/021,549 (the '549 Application). Applicant will submit terminal disclaimers based on the '026 Patent and the '549 Application upon indication of allowable subject matter, but for the double patenting rejection. Claim 37 is also rejected under obviousness-type double patenting over claim 15 of copending Application Serial No. 09/231,320 (the '320 Application). Applicant notes that claim 15 of the '320 Application was canceled in the Response to Restriction Requirement mailed October 3, 2000. Therefore, Applicant respectfully requests that this rejection be withdrawn.

Claims 23, 37-39, 43 and 44 are rejected under 35 U.S.C. §102(b) over Phillips U.S. Patent No. 4,955,856 (Phillips '856). Claims 1-17, 19-23 and 37-46 are rejected under 35 U.S.C. §102(b) over Jarvik U.S. Patent No. 5,376,114 (Jarvik '114). Claims 1-23 and 37-46 are rejected under 35 U.S.C. §103(a) over Phillips '856 in view of Jarvik and Koros et al. U.S. Patent No. 5,167,223. Jarvik '114 and Phillips '756 are directed to ventricular assist devices which require inflow of blood from the right or left ventricle. None of the cited references, alone or in combination, teach or suggest a device having first and second flow paths adapted to provide blood intake from a first location in an atrium or blood vessel and provide blood output at a second location in a blood vessel, thereby bypassing blood inflow from the right ventricle and the left ventricle, wherein the priming volume is not greater than about 1000 mls., as defined by amended independent claim 1 and new independent claims 47-49 and associated dependent claims. Further, the cited references, alone or in combination, do not teach or suggest a system wherein a cannula is adapted for insertion through the tricuspid valve, through the pulmonary valve, and a sufficient length into the pulmonary artery to prevent collapse of the right atrium, right ventricle or pulmonary artery and to maintain partial blood flow while the heart is displaced during surgery, wherein a controller controls a pump in response to physiologic parameters or wherein the pump removes blood from the vena cava or the right atrium and transports blood into the pulmonary artery, as defined by independent claims 19 (as amended) and 23 and associated dependent claims. In addition, the cited references, alone or in combination, do not teach or suggest a kit comprising a cannula system adapted for insertion through the tricuspid valve, pulmonary valve, and a sufficient length into the pulmonary artery to prevent collapse of the right atrium, right ventricle, or pulmonary artery and to maintain blood flow while the heart is lifted or displaced and wherein the cannula is adapted for intake of blood from the vena cava or the right atrium and output into the pulmonary artery, as defined by amended independent claim 37 and associated dependent claims. Nor do the cited references, alone or in combination, teach or suggest a kit in which a cannula is adapted at one end for insertion in the vena cava or right atrium and at the other end for insertion in the pulmonary artery, wherein the cannula is adapted for intake of blood from the vena cava or right atrium and output of blood into the pulmonary artery while the heart is displaced, wherein a pump communicates with the cannula for pumping blood from the vena cava or the right atrium to the pulmonary artery, as defined by independent claim 43 and associated dependent claims.

Claims 19 and 37 have been further amended to more particularly state the subject matter being claimed. In particular, the claims have been amended to clarify that the claimed subject matter is not limited to "bypass" surgery.

Claim 44 has been amended to correct a typographical error.

In view of the foregoing amendments and remarks, the case is believed to be in condition for allowance. Allowance of claims 1-23 and 37-49 is respectfully requested.

Respectfully submitted,

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Marked-Up V rsion of Am nd d Claims 1-3, 5-7, 12-14, 18, 19, 37, 39 and 44

1 (Amended). A system for circulating blood in a patient comprising:

a cannula enclosing first and second flow paths, the cannula adapted in length and size to extend through an incision into [a heart chamber or a blood vessel] the vena cava or the right atrium and adapted to provide blood intake at a first location in [a heart chamber or a blood vessel] the vena cava or the right atrium and provide blood output at a second location in [a heart chamber or a blood vessel] the pulmonary artery;

a pump communicating with the first and second flow paths and operating to intake blood through the first flow path at the first location and to output blood through the second flow path at the second location, thereby bypassing blood inflow from the right ventricle and the left ventricle;

wherein the pump and cannula, including the first flow path and the second flow path, having a combined priming volume external of the heart and [blood vessel] vena cava, and pulmonary artery of not greater than about 1000 ml.

2 (Amended). A system according to claim 1 or 47 wherein the priming volume is not greater than about 30 ml.

3 (Amended). A system according to claim 1 or 47 wherein the priming volume is not greater than about 10 ml.

5 (Amended). A system according to claim [1] 47 wherein the length of the cannula is adapted to extend through the bicuspid valve, through the aortic valve, and into the aorta.

6 (Amended). A system according to claim 1or 47 wherein the first and second flow paths comprise concentric lumens within the cannula adapted for insertion through a wall of the heart.

7 (Amended). A system according to claim 1 or 47 wherein the first and second flow paths are linear and adapted for insertion at [the] a first end into a heart chamber or blood vessel and at [the] a second end into a [second heart chamber or] blood vessel.

12 (Amended). A system according to claim [1] 47 wherein the length of the cannula is adapted to extend through an incision in the pulmonary vein and into the aorta, and the pump is adapted to convey blood from the pulmonary vein through the cannula into the aorta.

13 (Amended). A system according to claim [11] 1 further comprising:

a second cannula adapted to extend through an incision in the pulmonary vein or the left atrium and into the aorta, and a second pump adapted to convey blood from the pulmonary vein or left atrium through the second cannula into the aorta.

14 (Amended). A system according to claim 1 or 47 further comprising a controller

coupled to the pump for controlling the pump speed.

18 (Amended). A system according to claim 1 or 47 further comprising a cradle adapted for supporting the heart while displaced from its normal position and while the surgery is performed thereon.

19 (Amended). A system for preventing collapse of the right atrium, right ventricle or pulmonary artery and maintaining blood flow there through during beating heart [bypass] surgery comprising:

a pump and cannula system wherein the cannula is adapted for insertion through the tricuspid valve, through the pulmonary valve and a sufficient length into the pulmonary artery to prevent collapse of the right atrium, right ventricle or pulmonary artery and to maintain partial blood flow there through while the beating heart is lifted or displaced during surgery and wherein the pump and cannula are adapted for intake of blood [upstream of the pulmonary valve] from the pulmonary vein or the left atrium and output of blood into the pulmonary artery, while the beating heart is displaced during surgery; and

a controller for the pump adapted to control the pump in response to venous or pulmonic blood pressure, oxygen level, CO2 level or flow volume.

37 (Amended). A kit of parts for beating heart [bypass] surgery comprising:

a cannula system wherein the cannula is adapted for insertion through the tricuspid valve, through the pulmonary valve and a sufficient length into the pulmonary artery to prevent collapse of the right atrium, right ventricle or pulmonary artery and to maintain partial blood flow there through while the beating heart is lifted or displaced during surgery and wherein the cannula is adapted for intake of blood [upstream of the pulmonary valve] from the vena cava or the right atrium and output of blood into the pulmonary artery while the beating heart is displaced during surgery; and

a pump adapted for communication with the cannula and for pumping blood through the cannula from [upstream of the pulmonary valve] the vena cava or the right atrium to the pulmonary artery.

39 (Amended). A kit of parts according to claim 37 further comprising:

a cannula system wherein the cannula is adapted for insertion through the bicuspid valve, through the aortic valve and a sufficient length into the aorta to prevent collapse of the left atrium, left ventricle or aorta and to maintain partial blood flow there through while the beating heart is lifted or displaced during surgery and wherein the cannula is adapted for intake of blood [upstream of the aortic valve] from the pulmonary vein or the left atrium and output of blood into the

aorta while the beating heart is displaced during surgery; and

a pump adapted for communication with the cannula and for pumping blood through the cannula from [upstream of the aortic valve] the pulmonary vein or the left atrium to the aorta.

44 (Amended). A kit of parts according to claim 43 further comprising:

a cannula system wherein the cannula is adapted at one end for insertion through an incision in the pulmonary vein or the left atrium and adapted at the other end for insertion through an incision in the aorta to maintain blood flow there through while the heart is lifted or displaced during surgery and wherein the cannula is adapted for intake of blood from the pulmonary vein or left atrium and output of blood into the aorta while the heart is displaced during surgery; and

a pump adapted for communication with the cannula and for pumping blood through the cannula from the pulmonary vein or the left atrium to the aorta.